

Application No.: 10/065,868

REMARKS

Applicants wish to thank the Examiners for the personal interview conducted on 2/28/2006, where agreement was not reached with respect to patentable claims over the prior art of record. The interview was conducted in person and attended by Examiners Marjorie A. Moran and Marina I. Miller, and Applicants' representative William R. McCarthy III. The subject matter of the interview included a general discussion of the Examiners point of view regarding specific utility under 35 U.S.C. §101. Discussion also included the relationship of claim limitations to the prior art. In particular, Applicants described the invention of a user selecting to share the available number of probe sets of a custom probe array design with one or more other users. Applicants described an example where it is advantageous for a user who is only interested in a smaller number of probe sets than what is available on a custom probe array design to share the extra space and cost of the design with other users who select probe sets of interest that are also incorporated into the design. Applicants would like to state that the interview was found to be very helpful in advancing the prosecution of the present application.

Upon entry of this amendment claims 1-2, 4-9, 11-16, 19-23, 25-30, 33-35, and 84 are pending, and of these claims 1, 5, 19, 33, and 84 are independent. Applicants have cancelled claims 10, 17, 24, and 31.

Applicants have amended claims 1, 5, 19, 33, and 84 to include the limitations of: receiving a first selection from a first user of one or more probe set identifiers that identify a first set of probe sets each probe set comprising one or more probes, and a second selection from the first user to share available space on a custom probe array design with one or more additional users; identifying a second set of one or more probe

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sets from the one or more additional users; generating the custom probe array design comprising the first and second sets of probe sets, wherein the first and second sets of probe sets together comprise a number of probe sets that is less than or equal to a total number of probe sets available for the custom probe array design; the support for which may be found in paragraphs [0143]-[0144] of the present application. As discussed in the interview, Applicants understand that the Examiners version of the original specification electronically filed with the EPA VE software application may differ from the XML version the Applicants have. In the Applicants version paragraph [0143] begins on the 47<sup>th</sup> page, line 6 (paragraph begins with "Even if user 101 orders...").

In addition, claims 2, 14-15, 28, and 34 have been amended to incorporate language that Applicants believe clarify the scope of the claims. Also, claims 4, 6, 8, 12, 20, 22, 26, and 35 have been amended for consistency with the amendments made to the independent claim from which they depend. Applicants respectfully assert that the aforementioned amendments have been made for clarity or consistency and not for reasons related to the patentability.

Applicants assert that no new matter is presented by these amendments and respectfully request entry of the same.

Reply to Claim Rejections - 35 U.S.C. §101

Claims 1-2, 4-17, 19-31, 33-35, and 84 are rejected under 35 U.S.C. §101.

Applicants would like to thank the Examiners for their open discussion on utility under 35 U.S.C. §101 during the personal interview on 2/28/2006. Unfortunately, the

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Applicants do not agree with the Examiners position on utility given the current state of the law.

It is the Applicants understanding that the Examiner feels that a specific utility limitation must be recited in the claims, such as the example of a diagnostic limitation of a probe array provided by the Examiner.

Applicants respectfully disagree with such a position and respectfully assert that there is no requirement in the law for such specific utility limitations in the claims in order to satisfy the utility requirements. Rather, the current state of the law indicates that a practical utility of the claimed invention that is specific and substantial must either be obvious to one of ordinary skill in the related art or be asserted in the disclosure of the application. For example, the case of *Cross v. Iizuka* indicates that a claim meets the requirements for utility when there is evidence of practical utility, even though the claim does not recite any particular utility (See *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985)). The *Cross v. Iizuka* case further indicates that the requirement of substantial or practical utility is met if the utility is either obvious or discovered and disclosed in the application.

Applicants believe that the Examiners' position inappropriately attempts to place limitations upon the claims that are not supported by the current state of the law. Specifically, the Examiner is attempting to improperly limit the patentable subject matter of the claimed invention to one specific use. Applicants respectfully assert that a claimed invention is not required to be limited to one specific use, even when more than one specific use is disclosed. Applicants respectfully direct the Examiners attention to the case of *Ex parte Lanham* that involved an invention of a compound and process for

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making it that had two disclosed utilities, (1) a solvent and softening agent, and (2) an intermediate. The Board determined that the disclosure of a single utility was sufficient to meet the requirements for utility. (See *Ex parte Lanham*, 121 USPQ 223 (Pat. Off. Bd. App. 1958))

Applicants respectfully point the Examiner to the recently published (OG Notices: 22 November 2005) "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" document. The Interim Guidelines provide general guidance for the Examiner with respect to the subject of improperly placing limitations on subject matter that may be patented, where the placement of said limitations are not supported in the law. Applicants believe that such guidance has particular relevance to the question of whether a claim must recite specific utility limitations. For example, the paragraph from Section IV (A) refers to this:

The plain and unambiguous meaning of section 101 is that any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may be patented if it meets the requirements for patentability set forth in Title 35, such as those found in sections 102, 103, and 112. The use of the expansive term "any" in section 101 represents Congress's intent not to place any restrictions on the subject matter for which a patent may be obtained beyond those specifically recited in section 101 and the other parts of Title 35 . . . Thus, it is improper to read into section 101 limitations as to the subject matter that may be patented where the legislative history does not indicate that Congress clearly intended such limitations.

Alappat, 33 F.3d at 1542, 31 USPQ2d at 1556

Applicants respectfully assert that the Examiners position of requiring specific utility limitations in the claims contradicts the guidance set forth above. For example, the rulings in *Cross v. Iizuka* and *Ex parte Lanham* clearly indicate that a claim meets the utility requirements when at least one utility with a practical application is asserted in the

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disclosure. Thus, the Examiners position of requiring the claims to recite a specific utility in the limitations is improper.

Applicants would further like to point the Examiner to the guidance of the MPEP that pertain to determinations of asserted utility that are specific and substantial. MPEP §2107 (C)(1) states:

(1) Where the asserted utility is not specific or substantial, a prima facie showing must establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. The prima facie showing must contain the following elements:

- (i) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established;
- (ii) Support for factual findings relied upon in reaching this conclusion; and
- (iii) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

The guidance above clearly directs the Examiner to consider all asserted utility. Applicants also point out that said guidance does not give any suggestion that claims must recite limitations to specific utility. Instead, the guidance from the MPEP directs the Examiner to consider all relevant evidence of record as well as utilities taught in the closest prior art for an asserted utility.

As will be described in greater detail below, Applicants respectfully assert that a practical utility that is both specific and substantial for the presently claimed invention is both asserted in the description of the application, and obvious to one of ordinary skill in the art. Applicants acknowledge that the claimed invention as a whole must have an asserted use as set forth in section 101, and further discussed in Raytheon Co. v. Roper Corp. (See Raytheon Co. v. Roper Corp., 724 F.2d 951, 958, 220 USPQ 592, 596, 598-99

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(Fed. Cir. 1983), *cert. denied*, 469 U.S. 835, 225 USPQ 232 (1984)). Therefore, the question to be answered is: Does the claimed invention of probe arrays produced using a custom design, have at least one specific and substantial asserted use?

Applicants respectfully assert that it most certainly does.

For example, the Examiner has indicated that claim 2 meets the requirements for utility. Claim 2 further limits the probe arrays that are the result of claim 1 to a specific diagnostic use. In other words, the Examiner has indicated that claim 2 further limits the result of claim 1 to one specific utility (i.e. a diagnostic utility), and thus specific utility for claim 1 is asserted. Such assertions of at least one use for an invention to satisfy utility is consistent with the rulings in *Stiftung v Renishaw and Raytheon Co. v. Roper Corp.* (See *Stiftung v Renishaw PLC*, 945 F.2d 1173, 20 USPQ2d 1094 (Fed. Cir. 1991) and *Raytheon Co. v. Roper Corp.* referenced above).

Applicants also respectfully assert that the Examiner does acknowledge, but dismisses, an assertion of utility for probe arrays described in the application. In the Office Action mailed 2/10/2005 the Examiner states "such disclosed utility is not applicable to the instant claims" in reference to paragraph [0003] (In the Applicants version paragraph [0003] begins on the 2<sup>nd</sup> page, line 21 (paragraph begins after "Summary of Invention" header with "The expanding use of microarray...")) of the specification that states:

"More specifically, the data gained through microarray experiments is valuable to researchers because, among other reasons, many disease states can potentially be characterized by differences in the expression levels of various genes, either through changes in the copy number of the genetic DNA or through changes in the levels of transcription (e.g., through control of initiation, provision of RNA precursors, or RNA processing) of particular genes. Thus, for example, researchers use microarrays to answer questions such as: Which genes are

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expressed in cells of a malignant tumor but not expressed in either healthy tissue or tissue treated according to a particular regime? Which genes or EST's are expressed in particular organs but not in other? How does the environment, drugs, or other factors influence gene expression?"

Applicants respectfully assert that the above disclosure clearly sets forth specific and substantial utility for the claimed probe arrays. The Examiner has presented no arguments that the claimed probe arrays are different than the disclosed probe arrays, and thus there is no support for the Examiners assertion that the disclosed utility does not apply to the claims.

As an additional example Applicants respectfully direct the Examiners attention to MPEP §2107.01(C) that refers to the utility of research tools. Section §2107.01(C) illustrates the utility of similar inventions capable of analyzing compounds stating that the inventions have "a clear, specific, and unquestionable utility". In other words the MPEP describes the inventions as having utility based upon the analysis use without requiring a more specific use such as specifying the specific compounds to be analyzed or specific uses of the information produced from the analysis:

Some confusion can result when one attempts to label certain types of inventions as not being capable of having a specific and substantial utility based on the setting in which the invention is to be used. One example is inventions to be used in a research or laboratory setting. *Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds).* An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact "useful" in a patent sense. Instead, Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm. Labels such as "research tool," "intermediate" or "for research purposes" are not helpful in determining if an applicant has identified a specific and substantial utility for the invention.

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Along the same lines, Applicants also respectfully remind the Examiner that the bar for utility is not high where the invention is "useful" if it is capable of providing some identifiable benefit as discussed in *Juicy Whip Inc. v. Orange Bang Inc.* (See *Juicy Whip Inc. v. Orange Bang Inc.*, 185 F.3d 1364, 51 USPQ2D 1700 (Fed. Cir. 1999)).

Applicants respectfully assert that probe arrays are described in the application and are also well known in the art as capable of analyzing biological molecules such as nucleic acids, and that the results of said analysis clearly provide identifiable benefits to the public that include diagnostic and research benefits.

For the reasons described above, Applicants have shown that there is no requirement in the law for the claims to recite specific utility limitations. Applicants have further shown that specific and substantial utility for the claimed invention is asserted in both claim 2, the description in paragraph [0003], and further assert that it is known in the general state of knowledge of the art. If need be, Applicants will provide further examples of asserted utility but feel that it would be redundant to elaborate further because it is clear that utility is asserted in the examples already provided.

Therefore, Applicants respectfully assert that each of claims 1, 5, 19, 33, and 84 comply with 35 U.S.C. §101 and are thus patentable. Additionally, Applicants assert that each of claims 2, 4, 6-9, 11-16, 20-23, 25-30, 34-35 each depend from either claims 1, 5, 19, or 33 and are thus also patentable for the same reasons.

Reply to Claim Rejections – 35 U.S.C. §103

Claims 1-2, 4-17, 19-31, 33-35, and 84 are rejected under 35 U.S.C. §103(a) over Anderson et al. (WO 01/80155) in view of Kincaid (US 2003/0162183); claims 1, 5-8,

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11-13, 15-17, 19-22, 25-27, 29-31, 33-35, and 84 are rejected under 35 U.S.C. §103(a) over Tekagawa et al. (US 2004/0067488 as a translation of WO 02/61646) in view of Kincaid (US 2003/0162183); claims 2, 4, 14, and 28 are rejected under 35 U.S.C. §103(a) over Tekagawa et al. (US 2004/0067488 as a translation of WO 02/61646) in view of Cantor et al.(US 6,007,987) and further in view of Kincaid (US 2003/0162183); claims 8-10, and 22-24 are rejected under 35 U.S.C. §103(a) over Tekagawa et al. (US 2004/0067488 as a translation of WO 02/61646) in view of Garner (US 2003/0033290) and further in view of Kincaid (US 2003/0162183).

Applicants have amended claims 1, 5, 19, 33, and 84 to include limitations that none of the aforementioned references describe either alone or in combination. In particular, Applicants respectfully assert that none of the references describe the limitations of receiving a first selection from a first user of one or more probe set identifiers that identify a first set of probe sets each probe set comprising one or more probes, and a second selection from the first user to share available space on a custom probe array design with one or more additional users; identifying a second set of one or more probe sets from the one or more additional users; generating the custom probe array design comprising the first and second sets of probe sets, wherein the first and second sets of probe sets together comprise a number of probe sets that is less than or equal to a total number of probe sets available for the custom probe array design.

Applicants thus respectfully assert that each of claims 1, 5, 19, 33, and 84 are patentable and that each of claims 2, 4, 6-9, 11-16, 20-23, 25-30, 34-35 each depend from one of claims 1, 5, 19, 33, and 84 in their chain of dependency and are also patentable for

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the same reasons. Therefore, Applicants respectfully request that the rejections be withdrawn.

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CONCLUSION

In conclusion, Applicants have shown that each of claims 1-2, 4-17, 19-31, 33-35, and 84 have patentable utility under 35 U.S.C. §101 under the current state of the law. Applicants have also amended each of claims 1, 5, 19, 33, and 84 to include limitations that none of the references applied under 35 U.S.C. §103 disclose and thus respectfully assert that each are patentable. Further, since claims 2, 4, 6-17, 20-31, and 34-35 each depends from one of claims 1, 5, 19, or 33 in their chain of dependency each are thus patentable for the same reasons.

For these reasons, Applicants believe all pending claims are now in condition for allowance. If the Examiner has any questions pertaining to this application or feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at (781) 280-1522.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account 01-0431.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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